MR# 337631

August 5, 2011 **This Report CONTAINS Confidential Business Information**

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

8EHQ-08-17081

SUBJECT: TSCA 8(e)SUBMISSION

Dear Sir or Madam:

( ) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns ( ), an experimental pyrethroid insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is .

has imported for R&D on behalf of (" ").

The following reports concerning have been submitted to your agency: Two acute oral toxicity studies with rats (November 15, 2007: 8EHQ-07-16995 & 16996); a preliminary development toxicology study with rats (January 7, 2008: 8EHQ-08-17027); a micronucleus study with rats (February 19, 2008: 8EHQ-08-17081); an acute inhalation toxicity study in rats (July 11, 2007: 8EHQ-08-17209); a two week oral toxicity study in dogs (October 9, 2008: 8EHQ-08-17297); a micronucleus study with rats (February 16, 2010: 8EHQ-10-17866): an in-vivo unscheduled DNA synthesis (UDS) assay in rat hepatocytes (April 5, 2010: 8EHQ-10-17907); effects on pre- and postnatal development, including maternal function in rats (May 21, 2010: 8EHQ-10-17958); an in-vivo unscheduled DNA synthesis (UDS) assay in female rat hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); and a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166).

recently learned of new toxicological effects in a preliminary pharmacological study in rats and beagles. An outline of the study follows:

Effects of on the central nervous and cardiovascular system (preliminary study of general pharmacology study)
Tremors, twitches, startle (hyperreflexia) and impaired gait were observed int eh rats of the 250 mg/kg or higher groups. Convulsions, limb tone (absence of reaction), and salivation were observed in the rats of 500 mg/kg and higher groups. Pinna (absence of reaction) was observed in the rats of the 500 mg/kg group. Asthenic gait, tip toe gait, and incontinence of urine were observed in the rats of 1000 mg/kg group.

Salivation was observed in the male dogs of the 500 and 750 mg/kg groups.

believes that the clinical signs observed in this study are reportable under TSCA 8(e).

Performing Laboratory: Kumamoto Laboratory, Mitsubishi Chemical Medience Corporation

Study methods:
Animals: Crl:CD(SD) Rats; male and female, 6 weeks old; 3 animals/dose
Body weight: 124.5-135.1 g (male); 102.5-118.4 g (female)
Administration route; orally by gavage
Dosage levels: 0, 50, 250, 500, 1000 mg/kg
Dosing volume: 10 mL/kg
Vehicle: 0.5% methylcellulose aqueous solution
Pre-dosing fast: about 17 hours
Observation items: General condition and behavior (modified Irwin's test)
Observation period: 1,2,4,6,8,10, and 24 hours after administration

Results:
Mortality: Two of the three males in the 500 mg/kg group died. One of the three females in the 500 mg/kg group died. One male and one female of the 1000 mg/kg group died.

General condition and behavior: Piloerection and soiled fur, other than those noted above were observed in the males and females of the 1000 mg/kg group.

Study methods:
Dogs: Beagle dogs (telemetry implanted) males; 16 months old; 2 animals / dose
Body weight: 9.30 – 11.90 kg
Administration route: oral by capsule
Dose levels: 500, 750 mg/kg
Pre-dosing fast: about 17 hours
Observation items: clinical observations, blood pressure (systolic, diastolic and mean), heart rate and electrocardiogram (PQ interval, QRS duration QT interval and QTc)
Observation period: 1,2,4,6,8,10, and 24 hours after administration

Results:
Mortality: none in either group
Clinical observations: vomiting was observed in both the 500 and 750 mg/kg group.
Blood pressure and heart rate: systolic blood pressure, diastolic blood pressure, mean blood pressure and heart rate were increased in both the 500 and 750 mg/kg group.
Electrocardiogram: No treatment related changes were observed.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm

's efforts to commercialize this compound. Please refer to the attached letter of March 17, 2010 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Yours sincerely,

Technical Consultant

Encl.
cc: